

Hetcher

No. 05-1455

3/3/06

In the

United States Court of Appeals
for the Federal Circuit

SOLICITOR

MAR 7 2006

U.S. PATENT & TRADEMARK OFFICE.

IN RE RONALD A. SCHACHAR,

Appellant.

APPEAL FROM THE UNITED STATE PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES
APPLICATION SERIAL NO. 09/589,626

REPLY BRIEF OF APPELLANT SCHACHAR

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ARGUMENT

I. The Substantial Evidence Standard Does Not Convert The Record Into A Smorgasbord, From Which Some Pieces May Be Picked And Chosen While Others Are Disregarded.

The Solicitor argues that the test applicable to the substantial evidence standard of review merely requires evidence that a reasonable mind might accept as adequate to support a conclusion, and urges that the possibility of drawing inconsistent conclusions virtually requires that the Board's decision be sustained. Solicitor's Brief at 8–9, citing *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000); *In re Jolley*, 308 F.3d 1317, 1329 (Fed. Cir. 2002). However, the Solicitor then picks and chooses only that evidence supporting the position being urged, and urges the Court to disregard the remainder of the record.

A. The Solicitor Misstates The Applicable Test: The “Substantial Evidence” Standard Asks Whether A Reasonable Fact Finder Could Have Arrived At The Agency's Decision.

The Solicitor urges – in effect, if not in literal words – that the record be examined only to see if evidence supporting the Board's determination can be found within the record, and that contrary evidence be disregarded. However, the substantial evidence standard requires review of the record as a whole. The test cited by the Solicitor of “such evidence as a reasonable mind might accept as adequate to

support a conclusion” relates only to the requirement for the sufficiency of the evidence – whether the record contains “more than a mere scintilla,” or any evidence at all, supporting the Board’s determination. *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). The actual question asked in a substantial evidence review is whether a reasonable fact finder could have arrived at the agency’s decision based on the (closed) record under consideration. *Gartside*, 203 F.3d at 1312, *citing Consolidated Edison*, 305 U.S. at 229. Moreover, the substantial evidence review “involves examination of the record as a whole, taking into account evidence that both justifies and detracts from an agency’s decision.” *Gartside*, 203 F.3d at 1312, *citing Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487-88 (1951). Thus, once the sufficiency of the evidence within the record has been examined under the test cited by the Solicitor, the Court must then apply the substantial evidence test to determine whether the record as a whole supports the decision.

B. The Substantial Evidence Standard Does Not Allow An Arbitrary And Capricious Decision To Be Sustained.

The substantial evidence standard of the Administrative Procedure Act, 5 U.S.C. § 706(2)(E), is less deferential than the arbitrary and capricious standard thereof, 5 U.S.C. § 706(2)(A). *Gartside*, 203 F.3d at 1312, *citing American Paper Inst., Inc. v. American Elec. Power Serv. Corp.*, 461 U.S. 402, 412-13 n. 7 (1983) and

Abbott Lab. v. Gardner, 387 U.S. 136, 143 (1967). Thus an arbitrary and capricious decision cannot be sustained under the substantial evidence standard. Selective review only for supporting evidence and disregard of all contrary evidence as urged by the Solicitor would allow an arbitrary and capricious determination to be sustained on any record (e.g., that the world appears flat, when viewed from ground level), regardless of evidence to the contrary. Where, as here, the record taken as a whole compels a different conclusion than that reached by the Board, the substantial evidence standard requires that the decision NOT be sustained.

II. The Tube From Which A Hula Hoop Is Formed Has Ends; The Hula Hoop Itself Does Not.

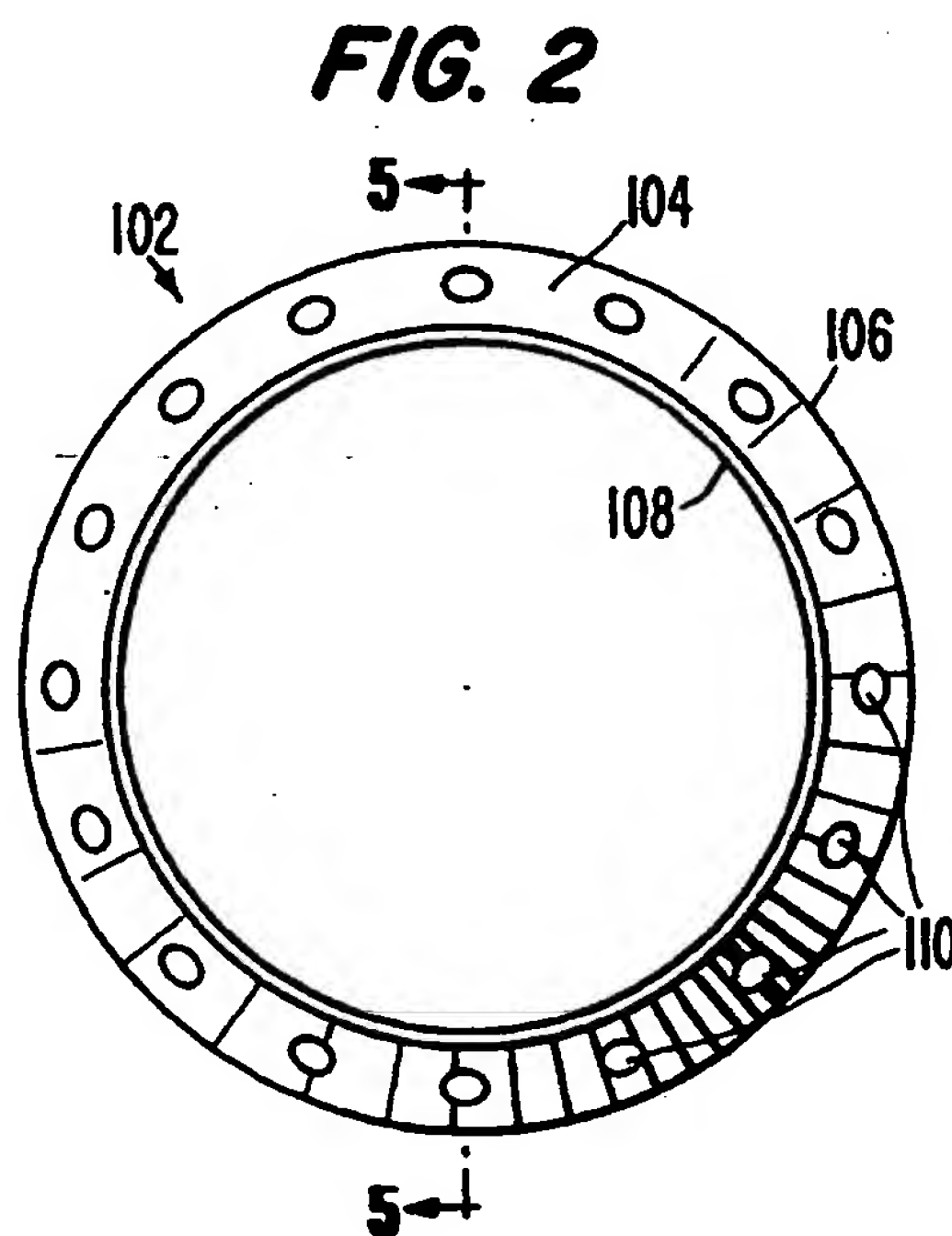
While the Solicitor cites hose clamps and belts, the unitary band formed as taught in the portion of the '331 patent relied upon by the Board is more analogous to a hula hoop. Formed from a length of plastic tubing with the ends joined together (by melting or adhesive), the completed hula hoop has no ends. Similarly, the continuous band in the '331 patent has no ends, even when formed from a strip of material having ends.

A “beginning” and an “end” may be arbitrarily defined for any continuous structure (circle, sphere, “doughnut” or annular ring, möbius strip, etc.). For continuous structures formed by joining two ends, such as a hula hoop or the

continuous band formed from a strip of material as disclosed in the '331 patent, the place of joinder may provide a convenient "mark" for such purposes. However the selection of such a point of joinder as the "ends" of the structure is as arbitrary as selection of any other point for the same purpose.

A. Selection Of "Ends" – A Wholly Unambiguous Term – In A Continuous Structure Is Inherently Arbitrary And Capricious.

The fallacy of asserting that a continuous structure has "ends" can be simply demonstrated. A plan view of the continuous band taught by the '331 patent appears below:



Where are the "ends" in the structure depicted?

Obviously any effort to identify a particular point within the continuous band depicted as the “ends” of that structure would involve arbitrary selection. Where the continuous band is molded, stamped, or otherwise formed as a unitary element, the assertion of some point around the circumference as “ends” is inherently arbitrary (and capricious). If, instead, the continuous band is formed by a strip of material having the ends joined as taught by the cited portion of the ‘331 patent, the selection of “ends” within the resulting structure remains inherently arbitrary even if the point selected corresponds to the ends of the strip of material used to form the continuous ring. Consider, for instance, an oval racetrack. Even though the track has straightaways and curves, the track itself has not beginning or ending point. A race begins and ends at certain points of the track merely because the race organizer selects a starting line and finish line. With the finish line, the race’s winner could not be determined since the track itself has no physical “end.”

Consider also a continuous band formed from multiple segments joined end-to-end: which end(s) of which segment(s) then forms the “ends” of the resulting structure? Or does the structure now have as many sets of ends as there are segments? Once the ends of a strip (or multiple segments) are joined to form a continuous band, any effort to distinguish some point along the circumference thereof as the “ends” involves arbitrary selection. The Board’s determination that the

continuous band structure of the '331 patent has "ends" is therefore inherently arbitrary and capricious.

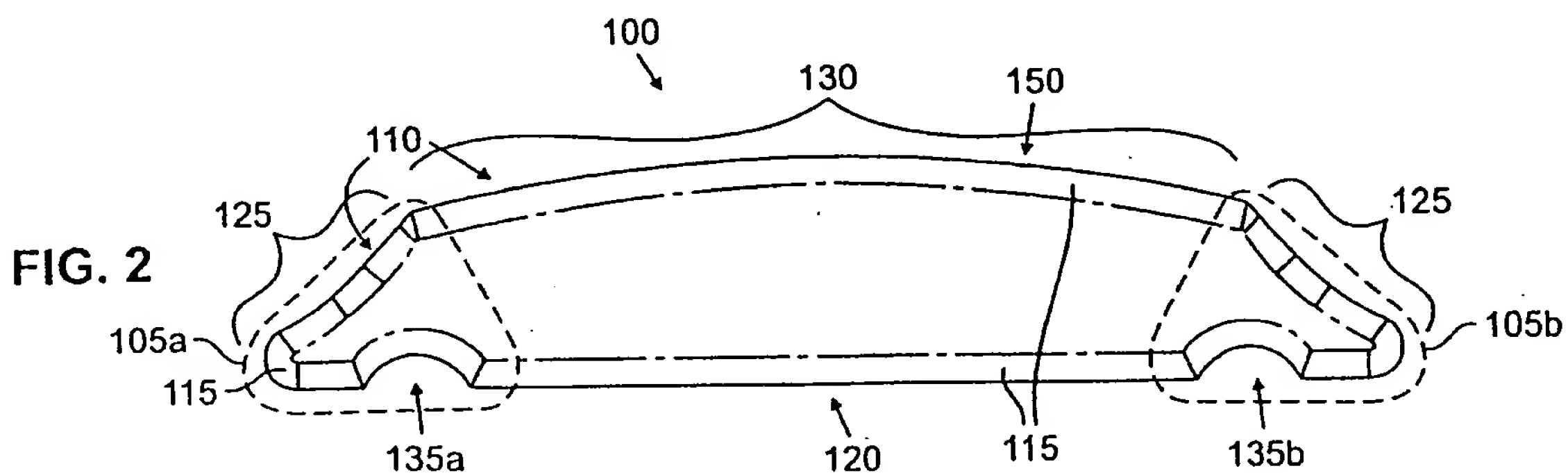
B. Where The Specification Compels, And The Applicant Has Unequivocally Adopted, A Narrow Interpretation, Reliance On A Broader Interpretation, Even If Reasonable, Is Arbitrary And Capricious.

The Solicitor urges that the Board's broad interpretation of the recited "ends" as being either free (unattached) or attached is "reasonable." However, even if the claims at issue could be construed so broadly as to apply to continuous structures, broad interpretations "must give way to the meaning imparted by the specification." *In re Johnston*, 435 F.3d 1381, 1384 (Fed. Cir. 2006), *citing Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). During prosecution and appeal to the Board, the applicant urged that the meaning of "ends," as properly interpreted in light of the specification, was inconsistent with the broader interpretation being adopted by first the Examiner and then the Board. A86–A87. Specifically, the applicant argued that based on the specification and drawings, the term "ends" refers to free and unattached ends, such that the claimed structure does not encompass a continuous band or ring as disclosed in the '331 patent.

The Board acknowledged the applicant's adoption of such an interpretation. A5 ("The claim neither requires the first and second ends to be free and/or unattached

nor excludes these ends from being fastened or attached.”); A12–A13. However, the Board dismissed that interpretation in favor of a broader interpretation supporting the determination of anticipation. A12 (“Claim 1 also does not exclude the prosthesis recited therein from being in the form of a closed circular ring.”).

The application as filed does, in fact, depict and describe a prosthesis having free and unattached ends 105a and 105b:



A45. Furthermore, various portions of the specification as filed compel the interpretation that the ends for the prosthesis as implanted into the eye and employed therein to treat presbyopia must be free and unattached, and are entirely inconsistent with a continuous structure of the type disclosed in the ‘331 patent. A36, lines 8–13 (ends of prosthesis facilitate insertion of prosthesis into scleral pocket); A37, lines 6–7 (ends of prosthesis may extend beyond scleral pocket); A39, claim 7 (ends fix body of prosthesis within pocket); A40, claims 10–11 (ends may have concave or convex shape).

Still further, during prosecution the applicant has unequivocally adopted an interpretation of the term “ends” as requiring free and unattached ends, precluding the claim from ever being read on a continuous structure such as that disclosed in the ‘331 patent by prosecution history estoppel. The applicant has therefore disclaimed the broader interpretation being relied upon by the Board.

Since the interpretation urged by the applicant is compelled by the specification and drawings, and since the applicant unequivocally disclaimed the broader interpretation proposed by the Examiner, the Board’s adoption of the broader interpretation was arbitrary and capricious.

III. The Solicitor’s Analogies To Belts and Hose Clamps Are Inapposite.

The Solicitor analogizes the continuous band formed from a strip of material as taught in the ‘331 patent to (a) a belt worn “to hold up a pair of pants,” and (b) a hose clamp. Solicitor’s Brief at 5, 8, 18. However, these analogies fail since both structures are continuous loops, and selection of the region of the buckle or adjusting screw as “ends” is arbitrary for the reasons described above.

In addition, the Solicitor seems to hope to suggest (without explicitly stating) that one or both ends of the band in the ‘331 patent might remain “free and unattached” after the continuous band is formed, in the same manner that the “tongue” of a belt may extend past the buckle or the end(s) of a hose clamp might

extend past the adjusting screw. The band, according to this subtext, could be formed from the strip of material having excess length, with free and unattached ends extending from the point(s) of joinder. Those skilled in the relevant art (and, in fact, anyone with common sense) will recognize that such a band would, when engrafted onto the surface of an eye as taught in the '331 patent, pose numerous risks including scratching of the eyelid's inner surface. Any excess length would obvious have to be removed or secured along the length of the continuous band.

The Solicitor repeats the Board's contention that the description of a strip of material with ends that may slide past one another (that is, the precursor or raw material from which the implanted prosthesis is formed) satisfies the claim. However, as previously discussed, the claim reads on the completed prosthesis actually operating on the sclera of an eye. To the extent that the claim is at all comparable to the embodiment in the '331 patent relied upon by the Board, completion of all circumferential adjustments to size the continuous band being formed, and fixing of the ends relative to each other (with excess length removed or secured), is necessary prior to engrafting of the resulting continuous band on an eye. Using the hula hoop analogy above, the continuous band disclosed in the '331 patent as effecting scleral expansion when engrafted onto the surface of an eye is akin a completed hula hoop, whereas the precursor described in the portion of the '331

patent relied upon by the Board decision equates to the length of tubing from which the hula hoop will be formed.

IV. The Solicitor's "Close Enough" Argument Regarding Expansion Of The Contacted Sclera.

On the issue of expanding the contacted portion of the sclera, the Solicitor notes that the primary embodiment disclosed in the '331 patent achieves scleral expansion (albeit by lifting an adjacent portion of the sclera). The alternate embodiment in the '331 upon which the Board relied relates to that primary embodiment, and presumably achieves scleral expansion in the same manner. That, according to the Solicitor, is sufficient to warrant the conclusions reached by the Board.

A. The Claims Require That The Recited Body Expand The Contacted Sclera, Not Merely That The Body "Contact And Expand" The Sclera.

The Solicitor's brief asserts:

There are two limitations recited in representative claim 1 that are material to this appeal: (i) the presence of a body having a first end and a second end, and (ii) the ability of that body to contact and expand the sclera. These limitations will be discussed, in turn, *infra*.

Solicitor's Brief at 9 (emphasis added). However, the claim limitation corresponding

to the underlined portion above actually requires that the prosthesis expand “said contacted sclera,” not merely that it “contact” and “expand” the sclera (perhaps independent, as in the ‘331 patent).

The primary embodiment disclosed in the ‘331 patent is a unitary (e.g., molded or stamped) continuous band. The ‘331 also discloses various alternative embodiments, such as the segmented band relied upon by the Examiner (but disregarded by the Board) and the continuous band formed from a strip of material.

The latter variant is one on which first the Examiner, and ultimately the Board, relied.

However, the record does not reflect that this variant differs from the main or primary embodiment of the ‘331 patent on the manner in which scleral expansion is achieved.

B. The Claim Requires Expansion Of The Contacted Portion Of The Sclera – With Or Without Sutures.

The Solicitor argues that the sutures used to lift the sclera in the ‘331 patent are not excluded by the claims under review. Solicitor’s Brief at 15–16. However, Dr. Schachar has never argued that the claims at issue exclude the use of sutures. Rather, Dr. Schachar pointed out that the ‘331 patent uses sutures to lift or pull up portions of the sclera adjacent to the contacted sclera instead of expanding the contacted portion of the sclera as claimed. Even if sutures are (also) employed, a

prosthesis otherwise satisfying the limitations of the claim would still infringe. However the resulting combination of the sutures and a prosthesis must still expanded the portion of the scleral contacted by the prosthesis, as recited in the claims.

C. The Issue Of Expanding The Contacted Sclera Was Addressed By Both Sides Below.

Contrary to the assertion by the Solicitor, the argument that the claim requires expansion of the contacted sclera, as opposed to other portions, was in fact addressed by both sides in the appeal to the Board. A61 (Appellant's Brief Under 37 C.F.R. § 1.192 arguing that claims require "a planform defining contact surfaces and at least one diameter so as to expand the sclera"); A77 (Examiner's Answer arguing that the '331 patent discloses a body "comprising . . . a planform that expands the contacted sclera).

V. — "Pay No Attention To The Man Behind The Curtain!" — The Solicitor's Remaining Arguments Highlight The Arbitrary And Capricious Nature Of The Board's Decision.

The Solicitor dismisses as "misleading and irrelevant" all evidence that is contradictory to the Board's decision: the discussion in the '331 patent regarding formation of the continuous band from multiple segments joined end-to-end, rather than from a single strip of material with the ends joined; the illustrative drawing of just such a structure from an issued, public record patent (US 6,579,316) issuing

based on a continuation-in-part application claiming priority to the '331 patent; and allowance of similar claims in an issued, public record patent (US 6,299,640) based on a co-pending application that was cross-referenced by and incorporated by reference into the subject application. Each of these items highlights the internal inconsistency and insupportability of the Board's determination.

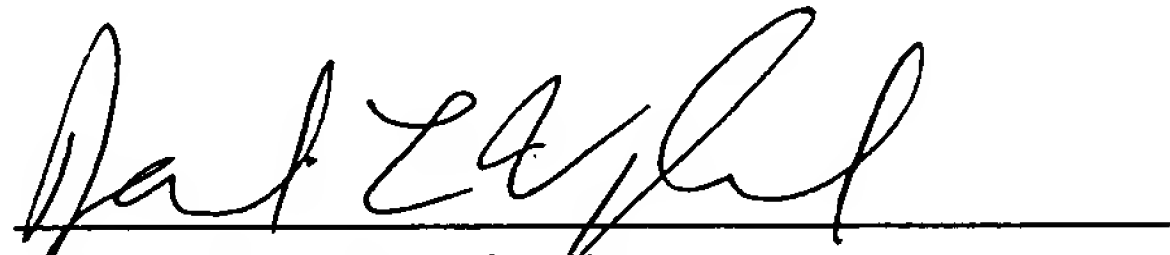
The Solicitor's argument that all such matters should be disregarded speak clearly to the arbitrary and capricious nature of the Board's decision. If portions of the record must be disregarded to reach the determination promulgated by the Board, it becomes self-evident that the record as a whole does not provide substantial evidence for the Board's decision.

CONCLUSION

When the record is viewed as a whole, the Board's decision is not supported by substantial evidence, but is instead arbitrary and capricious. The Board's decision should therefor be reversed.

Respectfully submitted,

DAVIS MUNCK BUTRUS, P.C.

A handwritten signature in black ink, appearing to read "Dan E. Venglarik", is written over a horizontal line.

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing REPLY BRIEF OF APPELLANT SCHACHAR and the concurrently filed APPENDIX are being served on the following parties by the methods indicated on March 3, 2006:

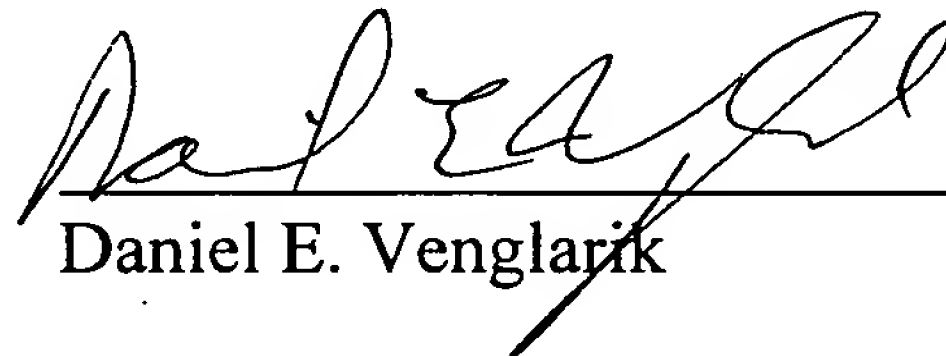
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